

Department of Defense
Pharmacoeconomic Center
1750 Greeley Rd., Bldg. 4011, Rm. 217
Fort Sam Houston, TX 78234-6190

MCCS-GPE

13 November 1998

MEMORANDUM FOR Assistant Secretary of Defense (Health Affairs)

SUBJECT: Minutes of the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee Meeting

1. In accordance with the Office of the Assistant Secretary of Defense (Health Affairs) [OASD(HA)] Policy 98-025, signed 23 March 1998, a meeting of the DoD P&T committee convened at 0800 hours on 13 November 1998, at Fort Sam Houston, TX.

2. MEMBERS PRESENT:

COL William D. Strampel, MC	Co-chairman
COL Errol L. Moran, MS	Co-chairman
COL Rosa Stith, MC	US Army Representative
LTC Judith O'Connor, MC	US Army Representative
Ms. Danielle Doyle, DAC	US Army Representative
CDR Terrance Eglund, MC	US Navy Representative
CDR Matt Nutaitis, MC	US Navy Representative
LCDR Denise Graham, MSC	US Navy Representative
LTC William Sykora, MC	US Air Force Representative
LtCol John R. Downs, MC	US Air Force Representative
LtCol (Sel) Greg Russie, BSC	US Air Force Representative
CDR Robert Rist	US Coast Guard Representative
Mr. John Lowe	VA Representative
LTC (P) George Crawford, MS	DMSB Representative
Capt Debra Parrish, BSC	DSCP Representative
Ms. Ray Nan Berry	Foundation Health Representative
Mr. William Hudson	Humana, Inc. Representative
Mr. Gene Lakey	TriWest Representative

3. OTHERS PRESENT:

COL Daniel Remund, MS	US Army
COL Ernest Sutton, MC	US Army

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LCDR Pamela Stewart-Kuhn	US Coast Guard
MAJ Mickey Bellemin, BSC	DSCP
LCDR Mark Richerson, MS	US Navy
Mr. Thomas Kellenberger	Merck-Medco Representative
Mr. Melvin Miller, DAC	US Army
Ms. Carol Scott, DAC	US Army
Mr. Shelby Tanner, SJA	US Army
Dr. Shana Trice, DAC	US Army

4. ISSUES DISCUSSED:

a. COL Strampel opened by stating that this will be his last meeting as co-chair since he is no longer at DoD and is now Chief of Staff for the Assistant Surgeon General of the Army at the Pentagon (1E518). At this time, no replacement has been named, however, COL Strampel stated that he would seek to get a replacement named prior to next meeting.

b. COL Moran introduced new attendees – COL Remund, PEC; MAJ Mickey Bellemin, who will be Capt Parrish's replacement at DSCP; Mr. Thomas Kellenberger, Merck-Medco (M-M); and LTC (P) George Crawford, Defense Medical Standardization Board (DMSB). COL Moran stated that this would also be his last meeting as a member of the committee. COL Dan Remund, Deputy Director for the PEC will assume COL Moran's role as co-chair.

5. OLD BUSINESS:

a. The committee reviewed the minutes from 14 July meeting. Two changes to be made: (1) On page 5, para 6(e)(i) - change "prenatal" to "prenatal with folic acid 1mg" and change "women" to "female"; and (2) On page 6, para (9) - add weight loss and dental products (Gel-Kam and Peridex). Minutes were approved with these changes.

b. LCDR Graham commented on the last meeting minutes posted on website - Navy facilities have requested a more detailed explanation for why the committee selected/deleted certain products. The committee agreed with this request. (CLOSED)

c. Financial disclosure statements (OGE Form 450) - Mr. Tanner stated that a few members of the committee have not submitted statements. He requested that those named individuals submit such statements as soon as possible. (OPEN)

d. Alternate P&T membership: Coast Guard - LCDR Pamela Stewart-Kuhn; Air Force - LtCol Arnyce Pock and MAJ George Jones; Navy - CDR Mark Brouker and Capt Michael Fredericks; VA - Mr. Ron Moser. Army alternates not yet provided. (OPEN)

e. Fertility drugs - limitations and guidelines: Capt Parrish stated that some women were on fertility drugs for two years without results. As the cost continues to escalate for these drugs, should we continue administering to women who are infertile? COL Strampel stated that

although this is a sensitive issue, a limitation policy should be implemented. The committee recommended that this issue be forwarded to Health Affairs for consideration of establishing a DoD-wide policy. (OPEN)

f. Migraine therapy: This issue was referred to the Clinical Practice Guideline (CPG) group to consider doing a migraine treatment guideline. Their response was that they had no plans to develop a clinical practice guideline for migraine treatment and this would be better served by a PEC dispensing guideline and an educational promotional piece. COL Moran stated that he might not have satisfactorily conveyed the committee's desire to the CPG group. The committee recommended that additional communication be sent to LTC Dolter at MEDCOM, to ask the group to rethink this issue. COL Strampel said that he would also call COL Sid Adkinson on this issue. LtCol (Sel) Russie stated that if this issue is still on the table in January/February, there will be three graduate students coming to the PEC who will need a project to work on. This could be something for them to work on and gather information for guidelines. (OPEN)

g. Policy for Viagra – The policy (HA Policy 98-040) was signed by Dr. Sue Bailey on 6 August 1998. COL Strampel stated that after the policy was released he expressed several concerns about the policy to Health Affairs and sought to write an implementation plan that would clearly outline the intent of the policy. The policy contains ambiguities and questionable provisions such as:

- It appears to open up the special order process at military pharmacies to providers outside the military treatment facility, which was never the intent. The special order process is reserved only for military treatment facility providers.
- Removes Viagra from the National Mail Order Pharmacy (NMOP) formulary which would force many patients to Standard CHAMPUS at a much higher cost to DoD or would possibly cause a switch to Caverject or Muse, also at a higher cost
- Reimbursement of only six tablets per month through Standard CHAMPUS may be unenforceable.

The general counsel agreed that the policy, as written, would cause problems and COL Strampel wrote an implementation policy, which was never sent forward by Health Affairs Clinical. The Air Force has sent out their own implementation guidance and the Army Surgeon General has endorsed the HA policy. COL Moran stated that Viagra prescriptions are currently being filled at the NMOP because of the expected release of an implementation plan that would have authorized doing so. Capt Parrish stated that if Viagra were removed from the NMOP formulary, it would produce thousands of calls per month by Merck-Medco (M-M) to physicians to seek a change to more expensive agents, in which case, most physicians would probably not authorize anyway. In an effort to ensure that NMOP patients meet the HA guidelines, the PEC will develop a one-page guideline sheet which M-M will then fax to the physicians who will sign and certify that all the clinical guidelines have been met and return form within 48 hours. If not returned within that timeframe, M-M will return the prescription and inform the patient that the physician did not fill out the paperwork to have it filled. The committee recommended that COL Strampel go back to Health Affairs/TMA and seek publication of an implementation plan that would eliminate the flaws in the policy as outlined above. (OPEN)

h. NMOP antibiotic dispensing policy: CDR Eglund circulated a list of antibiotics that were proposed to be exempt from the 30-day maximum quantity limitation. The committee limited the exemption for three agents (azithromycin, clarithromycin, and ciprofloxacin) to specific indications. Atovaquone and Cephalexin were deleted from the list. The committee approved the list as shown at Enclosure 1. (CLOSED)

i. Early refills - Capt Parrish stated that M-M has implemented a procedure to handle early refill requests. Refills that are submitted early will be input into their computer, but not be filled for mail out until the due date. As an example, if a refill is due on the 14th of the month and is sent in on the first, it will be entered and queued for mail out at the appropriate time. New prescriptions will be returned because there is no system in place to queue them for filling. Provisions have also been made for patients who call their prescription in too early. (CLOSED)

j. Oral contraceptives (21/28-day packages) - Capt Parrish stated that DSCP has asked manufacturers to reduce the prices for the 21-tablet packages to be comparable to the 28-tablet prices. Some price reductions have occurred, and some companies have not yet responded. (OPEN)

6. NEW BUSINESS:

a. Priority Review Drugs - Automatic NMOP and Basic Core Formulary (BCF)

Consideration: None of the agents listed below were added to the BCF. Decisions regarding the NMOP preferred drug list are outlined below:

1) Rebetrone® (combination of Rebetol® and Intron-A®) is currently mapped and being filled. **Add to NMOP** because it appears to offer a therapeutic advantage to interferon alone. Also **add to NMOP**, Roferon® and Infergen®.

2) Priftin® (rifapentine) - **Not added to NMOP** at this time. Wait until more usage has occurred before reconsidering. Mapped to rifampin.

3) Thalomid® (thalidomide) – **Exclusion from NMOP** due to restricted distribution requirements and mandatory testing requirements.

4) Preven® - **Exclusion from NMOP** due to time sensitivity of dosing.

5) Arava® (leflunomide) - defer decision pending evidence of usage and place in therapy. Will not be filled at NMOP at this time.

6) Sustiva® (efavirenz) – **Add to NMOP** because of indication.

7) Combivir® (lamivudine/zidovudine) – **Add to NMOP** because no more expensive than total cost of individual drugs. Committee recommended that **all oral retrovirals be added to NMOP**.

8) Xeloda® (capecitabine) – **Add to NMOP** because of indication. Committee recommended that **all oral antineoplastics be added to NMOP**.

9) Evista® (raloxifene) – **Add to NMOP** because of indication.

10) Plavix® (clopidogrel) – **Add to NMOP** because of indication and advantages to ticlopidine in aspects of dosing, monitoring requirements, and incidence of adverse effects..

11) Sulfamylon® (mafenide acetate powder) for 5% topical solution. **Not added to NMOP.** Cream is already on the NMOP. The solution has to be freshly prepared, so it is not a suitable dosage form for dispensing via the NMOP.

12) Detrol® (tolterodine) - Request from Naval Medical Center in Portsmouth to add to NMOP. Currently mapped to oxybutynin with a 20% success rate of switching. Currently, 370 patients are receiving 1mg or 2mg tablets through the NMOP. Although tolterodine has a slightly better side effect profile than oxybutynin, the committee voted to **not add to NMOP** because it is not more effective than oxybutynin and costs over four times as much.

b. Other NMOP Issues:

- 1) **Add to NMOP** – Rondec® oral drops because of listing on BCF.
- 2) **Add to NMOP** – Inhaler Spacers because of listing on BCF.
- 3) **Delete from NMOP** – Herplex® ophthalmic drops because no longer manufactured.
- 4) Mapping of agents by the PEC – drugs that have been mapped are: new angiotensin II receptor blocker candesartan (Atacand®) mapped to losartan, valsartan; new migraine agent rizatriptan (Maxalt® & Maxalt MLT®) mapped to sumatriptan; new SSRI citalopram (Celexa®) mapped to fluoxetine, sertraline, paroxetine; new low estrogen oral contraceptive Levlite® mapped to other oral contraceptives; mephobarbital (Mebaral®) mapped to phenobarbital; and mephenytoin (Mesantoin®) and ethotoin (Peganone®) mapped to phenytoin.

c. BCF Issues:

1) Non-steroidal ophthalmic agents – Fort Leavenworth requested a review of this class of drugs. Current BCF selection is flurbiprofen (Ocufen®), which lacks a primary care indication. Ketorolac (Acular®) would appear to be a more logical BCF selection because of its primary indication, however, it is more expensive than flurbiprofen. COL Moran also questioned if one is even needed for the BCF. It was suggested that local commands make their own selection. Mr. Lakey questioned the impact on the Managed Care Support contractors or inconvenience to patients. COL Strampel commented that removal of a drug from the BCF does not necessarily effect an MTF formulary because most facilities will more than likely keep an agent in this class on their local formulary. The committee removed Ocufen® from the BCF because it does not have a primary care indication that is necessary for inclusion on the BCF. The committee also did not recommend any other such agent for the BCF, preferring to let MTFs make their own choice.

2) Budesonide (Pulmicort®) and fluticasone (Flovent®) Oral Inhalers (see Enclosure 2): The committee approved the recommendation that budesonide and fluticasone oral inhalers be removed from the BCF for the reasons given in the enclosure. CDR Eglund opposed removal from the BCF because his facility advocates that it is more cost effective in a subset of patients. The remaining committee members agreed that it is possible that these agents may be more cost effective for certain patients requiring high doses. However, there is insufficient evidence in the literature to strongly support this claim, and the committee does not want to mandate that facilities have a drug available at 3 to 8 times the cost of equally effective agents. Also, this decision does not prohibit individual MTFs from including these agents on their local formulary. These agents will remain on the NMOP.

3) Consider removal of specific brand designation (i.e., Coumadin® brand only) from the BCF because an AB rated generic agent is available. The primary reason the BCF listed

“Coumadin® brand (Dupont) only” is historical in nature. Back in the days of the depot system, DMSB had designated a few items as “sole source”, meaning that only a designated brand could be purchased. At some point in time, Dupont brand warfarin was added as a “sole source” item. This listing carried over to the TriService Formulary (the predecessor to the BCF), then to the BCF. Also, there were not AB-rated warfarin products at that time. The first question is whether it is appropriate to have the brand name only designation on the BCF? Clinical evidence, from crossover studies, shows no difference in brand name vs. generic warfarin. Both are equally safe and efficacious according to the FDA. One initial difference is that Dupont-Merck, the maker of Coumadin®, came out with 3mg and 6mg strengths, which Barr, the maker of an AB-rated generic warfarin, did not have. However, Barr now does provide 3mg and 6mg strengths. Barr also does not currently provide the drug in unit dose packaging. Barr is anticipating providing unit dose packaging next spring. The generic tablets provided by Barr are scored, imprinted with the dosage strength, and are provided in the same color-strength combinations as the Dupont-Merck product. After discussion, the committee unanimously approved the removal of specific brand designation [i.e., Coumadin® brand (Dupont) only] from the BCF. The product will be listed on the BCF as “Warfarin oral”. With this change, MTFs are now free to make their own choice as to which warfarin product is provided at their facility. The second question asked was should DoD contract for a sole source warfarin product in order to provide uniformity of product availability throughout DoD and, at the same time, generate cost savings? The committee agreed that a contract for a sole source warfarin product for DoD, either unilaterally or jointly with the VA, should be sought. COL Remund suggested that the committee make an interim special designation for dispensing warfarin through the NMOP to avoid potentially switching patients from the brand name to the generic and back to the brand name (depending on which agent is selected for the contract). The special designation would be that switching NMOP patients to generic warfarin would be held in abeyance until the contracting issue is completed. No calls will be made on prescriptions for Coumadin®, they will be filled as written. If a prescription comes in as “warfarin” or “substitution allowed”, then the prescription can be filled with generic warfarin. The committee agreed. (CLOSED)

4) Long-acting nifedipine: Currently, the BCF states that all facilities must have a long-acting nifedipine on their formulary, the choices being either Adalat CC® or Procardia XL®. An MTF may have both on their formulary, however, they are not required to have both. COL Remund suggested that the PEC and DSCP go out for a blanket purchase agreement to identify the single form of nifedipine extended release that would be placed on the BCF without the closing the class. This would allow flexibility for MTFs who want both drugs and it would also achieve uniformity and possibly lower prices. Currently, the DAPA prices for Adalat CC® are \$0.46 per tablet for all strengths (30mg, 60mg, & 90mg). DAPA per tablet prices for Procardia XL® are \$0.65 for 30mg, \$1.18 for 60mg, & \$1.20 for 90mg. Since the VA has selected Adalat CC® as their preferred long-acting nifedipine and current prices favor Adalat CC®, COL Strampel recommended that the following be listed on the BCF: “Long-acting nifedipine (Adalat CC®) – class remains open. MTFs must have Adalat CC® on their formulary, but may choose to also have Procardia XL®”. Again, this will help to establish uniformity across DoD, yet, allow MTFs to also add Procardia XL® if they so desire. The committee agreed. The committee also agreed that only Adalat CC® should be listed on the NMOP. Procardia XL® will be removed from the NMOP Preferred Drug List. (CLOSED)

5) Angiotensin II Receptors - should one be included on the BCF? The committee does not support adding such an agent to the BCF because most patients can be successfully treated with an ACE inhibitor. Should DSCP seek BPAs with the manufacturers in an effort to obtain lower prices? The committee supported this strategy, however, one will not be placed on the BCF. (OPEN)

d. Contracting Issues:

1) Non-sedating antihistamines – seek price reductions through BPAs, but not for the purpose of putting one on the BCF. Motion passed. (OPEN)

2) Selective Serotonin Reuptake Inhibitors (SSRIs) – COL Sutton stated that the proposed strategy is to select one SSRI for placement on the BCF and NMOP. The SSRI class would remain open on the BCF and the NMOP. This strategy would ensure uniform availability of one SSRI throughout DoD. Local P&T committees could add additional SSRIs to their formularies as necessary to meet the clinical needs of patients and the preferences of MTF providers. The committee approved the proposed contracting strategy and five of the six proposed evaluation factors as presented by Mr. Miller. These evaluation factors may be contract sensitive, therefore, specific details are not provided in these minutes. (OPEN)

3) Proton Pump Inhibitors (PPIs) – COL Sutton stated that the proposed strategy is to seek a sole source contract through DPSC to select one PPI, either omeprazole (Prilosec®) or lansoprazole (Prevacid®), for the BCF and NMOP. The PPI class would be closed. This means that the selected agent will be the only PPI that will be dispensed through the NMOP and at MTFs. MTFs would still be able to utilize a local special order process for patients not successfully treated with the selected agent. Managed Care Support contractors would use the prior authorization process for prescriptions that are for the agent not selected. The NMOP contract does not allow for the prior authorization process, therefore, only the selected agent will be dispensed through the NMOP. The committee approved the strategy. (OPEN)

4) Glucose Test Strips – LtCol (Sel) Russie stated that the proposed strategy is to seek a sole source contract through DPSC to select one glucose test strip for the BCF and NMOP, with the class being closed. Five companies have made pre-solicitation presentations. The committee approved the proposed contracting strategy and the evaluation factors as presented by LtCol (Sel) Russie. These evaluation factors may be contract sensitive, therefore, specific details are not provided in these minutes. Target date for issuing the solicitation is January/February timeframe. (OPEN)

5) Fluoroquinolones – Does the committee think it's reasonable to have a fluoroquinolone on the BCF? One concern raised by LtCol (Sel) Russie was do we really want to mandate a fluoroquinolone on small facilities or clinics? The committee members agreed that every facility should have a fluoroquinolone on their formulary. A notation will be place on the BCF that will indicate that each facility must have a fluoroquinolone on their formulary. A specific fluoroquinolone will not be selected unless a clear choice can be made due to voluntary price reductions. Until a BCF selection is made, individual facilities will make their own choice as to which fluoroquinolone is carried on their formulary. (OPEN)

e. Other Issues:

1) Palivizumab (Synagis®) - Do we need prescribing guidelines for this agent? One issue is that some MTFs are/were sending patients downtown to obtain the drug and brought back to the hospital for administration. TriWest has had numerous communications with TMA to get this issue resolved, without success. COL Strampel will discuss this issue with the medical director of TMA. COL Strampel stated that it should be emphasized that if the hospital has responsibility for the primary care of the patient, they should be taking care of them and not sending them out. If the hospital does not have the capability for such treatment, which is unlikely, then, they should terminate their care and turn the patient over to the contractor. If the hospital is already providing the care, it is their responsibility to obtain the drug for the patient. Dr. Egland provided the committee with criteria for use of Synagis® and Respigam® that are being used at Naval Medical Center, Portsmouth, VA. LtCol (Sel) Russie recommended that these guidelines be attached to the minutes of this meeting to serve as a guide for developing local guidelines. The committee approved this recommendation (see Enclosure 3). (CLOSED)

2) Status of statins contract - COL Remund stated that DSCP issued the statin solicitation on 23 Oct 98. Offers are due on 23 Nov 98. The solicitation was issued without a final review by the PEC. DSCP is working on an amendment to correct various errors and modify certain clauses in the solicitation. DSCP may decide to extend the due date for offers. COL Remund reiterated the strategy that was approved at the last P&T meeting – the class will be closed and a minimum of one, maximum of two statins will be selected for the BCF and NMOP. Either atorvastatin or simvastatin will be selected in order to meet the needs of patients requiring large reductions in LDL-C. A contract will be established for a second statin if the addition of the second statin to the BCF and NMOP is predicted to be more cost-efficient than atorvastatin or simvastatin alone. (OPEN)

3) Request that quantity limitations which are in effect at the NMOP be equally applied to prescriptions filled by the TRICARE contractors. The committee position was that an appeal be made to TMA to allow this. COL Strampel stated that this was an issue going back to HA to ask if they will write a policy to do this as a first step. (OPEN)

4) COL Strampel raised the issue of flu shots for all the children in the world. Will this raise any problems or impact us? May become a bigger issue by next year. Put on the agenda for next meeting. (OPEN)

5) Capt Parrish raised one issue of a letter she received from TMA concerning non FDA-approved indications for some odd things such as Nizoral® for prostate cancer, Clomid® for men, tamoxifen for brain cancer, etc. COL Moran stated that current rules allow for filling of prescriptions for off-label use if there is literature substantiating such use. TMA said they would pay for it under standard CHAMPUS although CHAMPUS does not set forth who conducts the medical review and who makes the ultimate decision. The rules aren't very clear. The decision for the committee may be that because of the limited number of patients in this situation it would be beyond the scope of the NMOP to deal with. Therefore, prescriptions for off-label indications would not be filled by the NMOP, on a routine basis. (CLOSED)

7. ADJOURNMENT:

MCCS-GPE

SUBJECT: Minutes of the Department of Defense Pharmacy & Therapeutics Committee
Meeting, 13 November 1998

The meeting adjourned at 1215 hours. Location and date of next meeting has been set for 5 February 1999, 0800 hrs, at Health Affairs in Skyline Five. This will coincide with the TRICARE meeting, 1-5 Feb, in Washington, DC.

Enclosures

ERROL L. MORAN
COL, MS
Co-chairman

WILLIAM D. STRAMPEL
COL, MC
Co-chairman

Summary of BCF Changes

1. Additions:

Nifedipine long-acting (Adalat CC®) (see pg 6-7)

2. Deletions:

Budesonide (Pulmicort®) (see pg 5-6)

Flurbiprofen (Ocufen®) (see pg 5)

Fluticasone (Flovent®) (see pg 5-6)

Nifedipine long-acting (Procardia XL®) (see pg 6-7)

3. Other changes/notes:

Removal of “Coumadin® brand (Dupont) only” notation for Warfarin (see pg 6)

Removal of notation that MTFs must have one long-acting nifedipine. The long-acting nifedipine of choice is Adalat CC® (see pg 6-7)

Summary of NMOP Changes

1. Additions:

Combivir® (see pg 4)

Evista® (see pg 4)

Infergen® (see pg 4)

Inhaler spacers (see pg 5)

Plavix® (see pg 5)

Rebetron® (see pg 4)

Roferon® (see pg 4)

Rondec oral drops (see pg 5)

Sustiva® (see pg 4)

Xeloda® (see pg 4)

2. Deletions:

Herplex® ophthalmic drops (see pg 5)

Procardia XL® (see pg 6-7)

3. Exclusions:

Preven® (see pg 4)

Thalidomide (Thalomid®) (see pg 4)

4. Other changes/notes:

Approved list of antibiotics exempt from 30-day maximum quantity limitation (see pg 4)

Merck-Medco implemented procedure for handling early refill requests (see pg 4)

In future, all oral antineoplastics and oral retrovirals will be added automatically (see pg 4)

Some price reductions obtained on 21-day oral contraceptives (see pg 4)

Removal of Coumadin® brand only – patients not to be switched to generic, yet (see pg 6)